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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/740,698	12/19/2003	Sign Erickson Varner	56086 (71699)	3885

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EXAMINER	
MEHTA, BHISMA	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
10/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/740,698	VARNER ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68-120,122-127,129 and 132-138* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *68-120,122-127,129 and 132-138* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 15 2008 has been entered.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification fails to disclose the cap element being sized to provide a cross-section larger than the cross-section area of the coil or the zig-zag shape or the cross-section of the coil-shaped body member. Applicant's arguments in lines 20-24 of page 13 regarding the cap element being shown to be sized larger than the cross-section area of the coil or the zig-zag shape or the cross-section of the coil-shaped body member are persuasive. However, there is no disclosure in the specification of this specific language. Therefore, it is suggested that the specification be amended to include this specific language with reference to the figures indicated by Applicant.

The specification fails to disclose the cap element mating against the patient eye

outer surface (see claims 111 and 116). There is no disclosure of the cap element mating against the outer surface of the patient eye in the paragraphs cited by the Applicant or elsewhere in the specification.

The specification also fails to disclose the body member being in contact with intravitreal fluid. Applicant's arguments in line 25 of page 14 to line 2 of page 15 have been considered but are not persuasive as there is only disclosure of the non-linear shape geometry of the body member or the coil shape of the device providing a large intravitreal surface area. There is no disclosure of the body member being in contact with intravitreal fluid.

The specification fails to disclose the device being inserted through an incision smaller than the cross-section of the coil-shaped body member, the incision being smaller than the cross-section of the coil or zig-zag shaped body member, and the device being implantable within the patient eye through an incision smaller than the cross-section of the coil or zig-zag shaped body member.

Claim Objections

3. Claims 99-110, 116-120, 122-127, and 138 are objected to because of the following informalities: In claims 99 and 116, there appears to be a spelling error with the word "insicion". The dependency of claim 138 is unclear as it appears to be dependent from claim 7 which is a cancelled claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 68-91, 93-97, 99-109, 111-120, 122-127, 129, and 132-138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner et al (U.S. Patent No. 5,466,233) in view of Rosenman et al (U.S. Patent No. 6,478,776).

Weiner et al disclose an implantable drug delivery device having a non-linear shaped body member (12) comprising a tube and that is implanted within a patient to deliver a drug substance to the patient via the body member and a cap element (16) (see Figure 1). The cap element is sized to provide a cross-section larger than the cross-section of the non-linear body member such that the cap element abuts an incision through which the device is inserted to stabilize the device. The device is insertable through an incision approximately the same size as the outer diameter of the tube forming the body member (see Figure 14). The tube has a cross-sectional diameter approximately equal to that of an incision through which the device is being inserted (see Figure 14). With respect to claims 69-71, the device body member comprises at least five deviations from a linear path as seen by the multiple surfaces of the body member. The cap element is seen to be capable of being in contact with a patient eye outer surface when the body member is inserted into the eye. The cap element mates the body member at a proximal end of the device as seen in Figure 1.

The cap element is in contact with the body member. With respect to claim 76, Weiner et al disclose the device comprising a therapeutic agent for delivery to the patient during use of the device (line 33 of column 10 to line 27 of column 11). With respect to claims 77 and 78, Weiner et al disclose the device body comprising a polymer that comprises a therapeutic substance that can be delivered to the patient eye (lines 28-67 of column 8). With respect to claims 83-86 and 100-102, Weiner et al disclose a method of treating a patient comprising delivering a delivery device comprising a non-linear shaped body member (12) comprising a tube having at least five deviations from a linear path and a cap element (16) at a proximal end, inserting the device into a patient's eye through an incision, the incision being approximately the same size as the outer diameter of the tube forming the body member, whereby the body member resides in the patient's eye and the cap element remains outside the incision through which the device is inserted and abuts the outer surface of the eye to stabilize the device, and allowing a therapeutic agent to be administered to the patient via the body member. The cap element is seen to remain outside of and abut the incision as seen in Figure 14 where the device of Figure 1 is inserted into a patient eye such that the body member resides in the patient eye. With respect to claim 89 and 105, see line 33 of column 10 to line 27 of column 11. With respect to claims 90, 91, 106, and 107, the body member comprises a polymer and comprises a therapeutic substance that can be delivered to the patient eye (lines 28-67 of column 8). With respect to claim 108, the cap element is in contact with the outer surface of the patient eye. With respect to claim 109, the device is inserted by screwing the device into the eye. With respect to claim 116, Weiner et al disclose an

implantable ocular drug delivery device having a non-linear shaped body member (12) that is implanted within a patient eye during use of the device to deliver a drug substance to the patient eye via the body member and a cap element (16) (see Figure 1). The cap element is sized to prevent the cap element from passing through an incision through which the device is inserted and the cap element is configured to mate against the patient eye outer surface while the body member is inserted to the eye. With respect to claim 117, the incision comprises a sclerotomy. With respect to claim 118, the device is implanted in a minimally invasive surgical procedure. With respect to claims 119 and 120, the device is implanted at the pars plana and the body member is in contact with intravitreal fluid (lines 29-50 of column 5 and line 24 of column 14 to line 5 of column 16). With respect to claims 122-127 and 132-137, see line 46 of column 8 to line 52 of column 9 and line 65 of column 9 to line 32 of column 10. With respect to claim 138, the tube has a circular cross-section.

Weiner et al disclose the implantable drug delivery device substantially as claimed. Even though Weiner et al disclose a non-linear shaped body member comprising a tube, Weiner et al are silent on the specifics of the tube of the body member comprising a coil or zig-zag shape or being wound into a coil shape. Rosenman et al disclose a delivery device having a non linear shaped body member (12) comprising a tube provided in a coil or zig-zag shape that is implanted within a patient and a cap element (56) which abuts an incision through which the device is inserted to stabilize the device (see Figures 18 and 19). The device is insertable through an incision approximately the same size as the outer diameter of the tube

forming the body member (see lines 62-67 of column 10 and lines 16-26 of column 11). The device body member comprises a helical shape or a substantially Z-shape as seen in Figures 18 and 19. Rosenman et al disclose implanting the device within the heart and other organs of the body which can include the eye (lines 8-28 of column 16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tube forming the body member of Weiner et al with a coil or zig-zag shape as taught by Rosenman et al as Rosenman et al disclose that it is well known to provide an implantable device with a coil or zig-zag shape so that the device can be properly positioned and maintained in the desired location in a patient's body. Since the device of Rosenman et al is insertable through an incision approximately the same size as the outer diameter of the tube forming the body member, providing the tube forming the body member of Weiner et al with a coil or zig-zag shape would result in the device of Weiner et al being insertable through an incision approximately the same size as the outer diameter of the tube forming the body member.

As to claims 79-82, and 129, Weiner et al disclose the drug delivery device substantially as claimed. However, Weiner et al are silent on the specifics of the body member comprising a tube wound into a coil shape. Rosenman et al disclose an implantable drug delivery device having a body member (12) comprising a tube wound in a coil or shape as seen in Figures 18 and 19. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the tube forming the body member of Weiner et al with a coil shape as taught by Rosenman et al as Rosenman et al disclose that it is well known to provide an implantable device with a

coil shape so that the device can be properly positioned and maintained in the desired location in a patient's body. Since the device of Rosenman et al is insertable through an incision approximately the same size as the outer diameter of the tube forming the body member, providing the tube forming the body member of Weiner et al with a coil or zig-zag shape would result in the device of Weiner et al being insertable through an incision approximately the same size as the outer diameter of the tube forming the body member.

As to claims 93-97, 99-109, and 116, Weiner et al disclose the device and method substantially as claimed. However, Weiner et al are silent on the specifics of the body member being coil-shaped or zig-zag shaped where the device is inserted through an incision smaller than the cross-section of the coil-shaped body member. Rosenman et al disclose an implantable drug delivery device having a coil-shaped or zig-zag shaped body member as seen in Figures 18 and 19 where the device is inserted through an incision smaller than the cross-section of the coil-shaped or zig-zag shaped body member (see lines 62-67 of column 10 and lines 16-26 of column 11). The device body member comprises a helical shape or a substantially Z-shape as seen in Figures 18 and 19. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the body member of Weiner et al with a coil shape or zig-zag shape as taught by Rosenman et al as Rosenman et al disclose that it is well known to provide an implantable device with a coil shape or zig-zag shape so that the device can be properly positioned and maintained in the desired location in a patient's body. Since the cap element of Weiner et al is sized to provide a cross-section

larger than the cross-section of the non-linear body member, providing the body member of Weiner et al with a coil shape would result in the cap element of Weiner et al being sized to provide a cross-section larger than the cross-section of the coil-shaped body member.

6. Claims 92, 98, and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner et al in view of Rosenman et al as applied to claims 83, 93, and 99 above, and further in view of Johnson. Weiner et al and Rosenman et al disclose the method substantially as claimed. However, Weiner et al and Rosenman et al are silent on the specifics of the device comprising a shape memory material. Johnson discloses an implantable drug delivery device with a non-linear body member that can be made of nitinol, a very well known shape memory alloy of nickel-titanium (lines 39-56 of column 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Weiner et al and Rosenman et al to make the device of a shape memory material as taught by Johnson as Johnson teaches that it is well known to make an implantable device from a shape memory material to provide a bio-compatible and strong device.

Response to Arguments

7. Applicant's arguments with respect to claims 68-120, 122-127, 129, and 132-135 have been considered but are moot in view of the new ground(s) of rejection.

8. Upon further review, the objection to the oath and declaration as being defective is withdrawn and, therefore, a new oath or declaration is not required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
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